Original article

Clinical algorithms for the screening of pregnant women for STDs in Libreville, Gabon: which alternatives?

A Bourgeois, D Henzel, G Malonga-Mouelet, G Dibanga, C Tsobou, M Peeters, E Delaporte

Objective: Sexually transmitted diseases (STDs) remain one of the major public health problems in the developing world. To implement a systematic screening of STDs among pregnant women in Libreville, Gabon, a preliminary cross sectional study on STD prevalence and risk factors was performed in antenatal clinics. A score, integrating risk factors and elementary clinical signs for the screening of STDs, showed higher performances compared with hierarchical algorithms. The prospective validation of this score based on six criteria (risk factors and simple clinical signs) was done in 1994–5. The sensitivity (76.7%), compared with results from other studies, was acceptable for diagnosing cervical infection (*Neisseria gonorrhoeae* and/or *Chlamydia trachomatis*) but the specificity was low (50.6%). In addition, the diagnostic values for diagnosing vaginal infection (*Trichomonas vaginalis* and/or *Candida albicans)* were poor. We then proposed to evaluate an alternative flowchart for the screening of cervical and vaginal infections.
Methods: In this study, 646 pregnant women were enrolled. Each woman was interviewed and examined by a physician and then was subjected to reference laboratory examinations. An algorithm in two steps, combining a risk assessment score at the beginning of a hierarchical process, followed by a second step more specifically applied to a limited number of women, was developed and evaluated.
Results: The prevalence rate was 11.3% for cervical infection and 39.5% for vaginal infection. The first step of the algorithm, applied to all pregnant women, is based on four criteria (age, marital status, dyspareunia, coloured vaginal discharge). It allows classification of the women into three classes: high, low, and intermediate risk of cervical infection. Only the patients with intermediate risk were submitted to further investigations including speculum and microscopic examination, and subsequently chlamydial antigen detection. This flowchart was 83.6% and 81.2% sensitive and 63.4% and 62.7% specific for predicting cervical infection and vaginal infection, respectively.
Conclusion: Similar strategies using simple rapid tests for chlamydial and gonococcal infection would certainly constitute a good diagnostic tool. This theoretical model needs to be evaluated prospectively, not only to confirm their diagnostic value but also to evaluate their feasibility, reliability and acceptability, as well as their cost effectiveness.
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Programme SIDA de l'ORSTOM, Montpellier, France
A Bourgeois
M Peeters
E Delaporte

INSERM U13, Paris, France
D Henzel

Programme National de Lutte contre le SIDA, Libreville, Gabon
G Malonga-Mouelet
G Dibanga
C Tsobou

Correspondence to:
E Delaporte, Programme SIDA, 911 Avenue Agropolis, BP 5045, 34032 Montpellier cdx 1, France.

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Introduction

Sexually transmitted diseases (STDs) remain one of the major public health problems in the developing world. This is so because STDs enhance the sexual transmission of HIV,[1 2] and also because of the morbidity and mortality rates of STDs among women and children.[3–6]

Sociocultural and clinical factors[7 8] pose particular challenges for the control of STDs. In developing countries, moreover, the lack of laboratory facilities or qualified staff and limited financial resources are other constraints.

In such situations, the World Health Organisation (WHO) has recommended for the management of STDs the syndromic approach,[9 10] which allows the treatment of patients at the first consultation. For this syndromic approach, an algorithm is used which can be hierarchical, based on successive and logical steps, or non-hierarchical based on a risk factors score. This approach is not dependent on the laboratory results, and could be cost efficient. The major drawback of the syndromic approach is that patients with asymptomatic infections are not detected.

Furthermore, different reports on the evaluation of algorithms for vaginal discharge have shown a poor diagnostic value even using a risk score, so the use of such algorithms remains questionable.[11 12]

In Gabon, STD prevalence rates among pregnant women are very high and the infertility rate due to STDs is one of the highest observed in Africa.[13–15] This justifies the systematic screening for the most important and frequent STDs, which include gonococcal, chlamydial, trichomonal, and candidal infections.[16]

Even if *Candida albicans* infections are vaginal infections more often and not sexually transmitted, they are classically considered with other STDs, in particular in the WHO management guide for STDs.[9 10] As one objective of this study was the evaluation of the WHO recommendation we kept to this classification. In order to implement systematic STD screening among pregnant women visit-

ing dispensaries in Libreville, the capital of Gabon, a preliminary cross sectional study was performed. From this study, a flowchart based on a score favouring the diagnosis of cervical infection was selected. The prospective evaluation of this flowchart was done in 1994–5[17] among pregnant women presenting for their first antenatal visit.

In this population, gonococcal or chlamydial cervical infection was found in 11.3% of the cases, and trichomonal or candidal vaginal infection in 39.5% of the cases. The performances of this score were unsatisfactory for diagnosing cervical infection with a sensitivity of 76.7% and a specificity of 50.6%. Positive and negative predictive values were 17.3% and 94.1% respectively.

Based on this result, and before the widespread use of this strategy, we proposed to evaluate a new algorithm with higher specificity for cervical infection and higher sensitivity for vaginal infection. We report here the development of this new algorithm in two steps, combining a risk assessment score and a hierarchical process.

Methods

POPULATION

The study was conducted among pregnant women attending three antenatal clinics in Libreville between November 1994 and March 1995. During this period, all women presenting consecutively for their first antenatal visit were recruited. Well informed consent was obtained before inclusion in this study. In all the clinics each woman was interviewed and examined by the physician. From the interview, demographic data, sexual and gynaeco-obstetric history, and current STD symptoms were collected. Physical examination included inspection with a speculum. Serum samples and cervicovaginal swabs were collected for the reference laboratory tests.

DEFINITIONS AND LABORATORY DIAGNOSIS

Cervical infection was restricted to gonococcal and/or chlamydial infection, vaginitis to candidal and/or trichomonal infection.[9 10] *N gonorrhoeae* was identified by culture on modified Thayer–Martin medium or by presence of Gram negative diplococci at direct examination of a cervical smear. A second endocervical specimen was tested for direct chlamydial antigen detection with Micro-Track EIA (Syva). The presence of *Trichomonas vaginalis*, yeast forms, clue cells, and leucocytes was determined by direct microscopic examination of a wet mount and after Gram coloration. Sera were evaluated for syphilis reactivity with rapid plasma reagin test (RPR, Becton Dickinson). All the tests were done in the same laboratory.

PARTNER NOTIFICATION AND TREATMENT

During the antenatal visit, women received counselling on STD prevention. They came back for laboratory results 1 week later and adequate treatment was given (if necessary), according to the WHO recommendations. They were encouraged to refer their partner(s) for examination and (or) treatment. The women could also receive the treatment for their partners.

PRINCIPLE USED FOR THE CONCEPTION OF NEW ALGORITHMS

The previous evaluated flowcharts[16 17] had limited specificity for diagnosing cervical infection and a low sensitivity for the diagnosis of vaginitis. The main objective of such flowcharts is to detect cervical infections with a high sensitivity because of their complications. However, the detection of vaginal infections (being very prevalent) is also important. To increase the specificity of the flowchart for diagnosing the cervicitis, without reducing the sensitivity, we developed algorithms in two steps, combining a risk assessment score at the beginning of a hierarchical process, followed by a second step more specifically applied to a limited number of women.

The first step, applied to all pregnant women, aims to classify the patients into three categories: patients with low, intermediate, or high probability of cervical infection. This step is based on a risk assessment score using only very simple criteria as risk factors or simple clinical signs chosen for their feasibility and reproducibility by all midwives. Women with high risk of cervicitis will be treated immediately for cervical infection, whereas women with low risk will be further investigated for vaginitis only. Women with intermediate risk will be submitted to a second step, for the search of additional signs of cervical infection, as well as vaginal infection. The criteria used in this second step have to be more specific for the diagnosis of cervicitis, and more sophisticated tests, depending on the availability of facilities, can be used.

DATA ANALYSIS

DBASE and EPI-INFO were used for entry, management, and data analysis. Differences in rates were tested with χ^2 test. Intensity of link between characteristics and cervical or vaginal diseases was estimated by the odds ratio.

Results

GENERAL CHARACTERISTICS

In this study, 646 pregnant women were examined by the physician in three antenatal clinics: 267 in Awendje, 239 in La Peyrie, 140 in Glass. The mean age of the women was 23.6 years (median age 23 years, interquartile 19–27); 28.8% were married, 25.1% single, and 45.4% lived in free union. A total of 21.5% of the women declared the use of condom at least once, but only 4.8% regularly; 12.8% of the women declared another partner than the father of the baby in the past year; 66% reported previous symptoms suggestive of STDs (vaginal discharge, genital ulcers, or micturition burn), but only 33% of them had healthcare seeking behaviour.

STDS PREVALENCE AND RISK FACTORS OR SIGNS

In this population, 73 cervical infections (11.3%) were diagnosed, including 12 cases of *Neisseria gonorrhoeae* and 64 cases of *Chlamydia*

Table 1 Vaginal infections and prevalence rate of STDs (case number) among pregnant women attending different antenatal clinics.Libreville, Gabon, 1994–5

	Awendje (n=267)	*La Peyrie (n=239)*	*Glass (n=140)*	*Total (n=646)*
	% (n)	*% (n)*	*% (n)*	*% (n)*
N gonorrhoeae	1.1 (3)	1.7 (4)	3.6 (5)	1.9 (12)
C trachomatis	12.0 (32)	7.9 (19)	9.3 (13)	9.9 (64)
T vaginalis	10.5 (28)	11.3 (27)	10.0 (14)	10.7 (69)
C albicans	26.6 (71)	35.1 (84)	31.4 (44)	30.8 (199)
Clue cells	22.8 (61)	28.5 (68)	13.6 (19)	22.9 (148)
Syphilis (RPR)	4.1 (11)	0.8 (2)	4.1 (6)	2.9 (19)

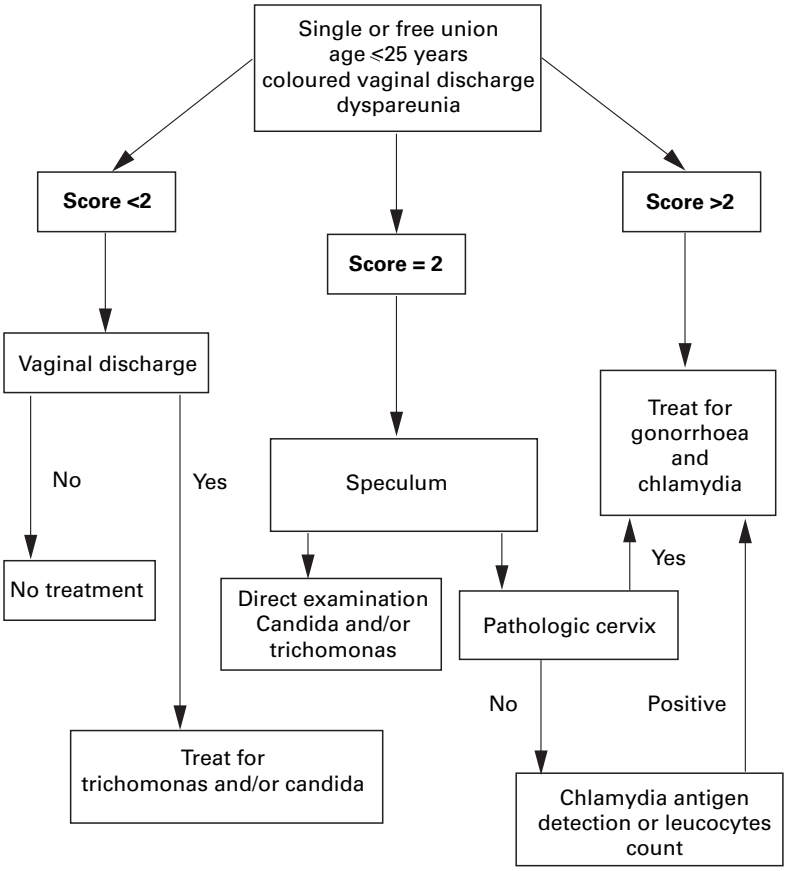

Figure 1 New algorithm for the screening of pregnant women for STDs in Gabon.

trachomatis, 255 vaginal infections (39.5%) including 69 of trichomoniasis and 199 of candidiasis (table 1). Syphilis seroreaction by RPR was positive in 19 cases (2.9%).

Risk factors and clinical signs associated with chlamydial or gonococcal infection are shown in table 2. Variables significantly associated with cervical infection were marital status (living single or in free union), age ⩽25 years, vaginal discharge (by interview and inspection), coloured or malodorous discharge, and at least one alteration of the cervix by speculum examination (table 2). Dyspareunia (defined as pelvic pain during sexual activity) was reported in 32.9% of women with laboratory proved cervical infection and 26.2% of women without such infection, but this difference was not significant at the 95% confidence level.

Signs well correlated with trichomonal or candidal infection were vaginal discharge by inspection, and vaginal itching (table 3).

ELABORATION OF ALTERNATIVE FLOWCHARTS (FIG 1)

Choice of criteria included in the first step was guided by their odds ratio level, their simplicity, and reliability. Only three criteria had an odds ratio greater than two: marital status, age, and colour of vaginal discharge. In combining the criteria together and in order to preserve a good sensitivity, it was necessary to add another criterion independent of the preceding ones. Dyspareunia (OR=1.4) was chosen instead of reported or observed vaginal discharge (OR>1.6), (already included in the criterion << coloured discharge). For a widespread utilisation of such flowcharts by primary healthcare workers, we have intentionally limited the number of criteria to four. The threshold choice was guided by two constraints: the acquiring of the highest sensitivity compatible with a restricted number of patients (later submitted to a second step, more specific

Table 2 Risk factors and signs prevalence rate (case number), and relation with gonococcal or chlamydial cervical infection among pregnant women.Libreville, Gabon 1994–5

	Population (n=646)	*Cervical infection*			
Signs	*% (n)*	*Yes (n=73) % (n)*	*No (n=573) % (n)*	*OR (95%CI)*	*p Value*
Interview:					
Single or free union	70.5 (455)	86.3 (63)	68.4 (392)	2.9 (1.4-6.2)	*0.002*
Age ⩽25 years	68.0 (439)	82.2 (60)	66.0 (379)	2.4 (1.2–4.7)	*0.006*
>1 sex partner in the last year	12.8 (83)	16.4 (12)	12.4 (71)	1.4 (0.7–2.8)	0.33
Condom use	21.5 (139)	24.7 (18)	21.1 (121)	1.2 (0.7–2.2)	0.49
Reported vaginal discharge	51.1 (330)	61.6 (45)	49.7 (285)	1.6 (0.9–2.8)	*0.05*
Pelvic pain	37.6 (243)	38.4 (28)	37.5 (215)	1.0 (0.6–1.8)	0.89
Lumbar pain	23.7 (153)	26.0 (19)	23.4 (134)	1.2 (0.6–2.1)	0.62
Pelvic or lumbar pain	44.6 (288)	47.9 (35)	44.2 (253)	1.2 (0.7–2.0)	0.54
Dyspareunia	26.9 (174)	32.9 (24)	26.2 (150)	1.4 (0.8–2.4)	0.22
Clinical signs:					
Vaginal discharge	38.2 (247)	53.4 (39)	36.3 (208)	2.0 (1.2–3.4)	*0.005*
Coloured discharge	15.5 (100)	27.4 (20)	14.0 (80)	2.4 (1.3–4.3)	*0.003*
White discharge	22.6 (146)	26.0 (19)	22.2 (127)	1.2 (0.7–2.2)	0.46
Malodorous discharge	4.2 (27)	8.2 (6)	3.6 (21)	2.4 (0.8–6.5)	*0.07*
Speculum examination:					
Cervix suppuration	11.8(76)	16.4 (12)	11.2 (64)	1.6 (0.8–3.2)	0.19
Cervix ulceration	3.9 (25)	1.4 (1)	4.2 (24)	0.3(0.02–2.3)	0.24
Cervix inflammation	25.9 (167)	38.4 (28)	24.3 (139)	1.9 (1.1–3.3)	*0.01*
Cervix friability	5.1 (33)	8.2 (6)	4.7 (27)	1.8 (0.6–4.9)	0.2
At least 1 cervix alteration	37.6 (243)	47.9 (35)	36.3 (208)	1.6 (1.0–2.7)	*0.05*
At least 2 cervix alterations	8.2 (53)	13.7 (10)	7.5 (43)	2.0 (0.9–4.3)	*0.07*
Microscopic examination:					
Leucocytes ⩾ 10/field	11.0 (71)	47.9 (35)	34.0 (195)	1.8 (1.1–3.1)	*0.02*

Table 3 Clinical signs prevalence rate (case number) among pregnant women with and without trichomonal or candidal vaginal infection. Libreville, Gabon, 1994–5

Signs	Population n=646 % (n)	Vaginal infection: Yes (n=255) % (n)	Vaginal infection: No (n=391) % (n)	OR (95%CI)	p Value
Interview:					
Vaginal discharge	51.1 (330)	51.4 (131)	50.9 (199)	1.0 (0.73-1.42)	0.91
Vaginal itching	33.7 (218)	38.4 (98)	30.7 (120)	1.41 (0.99-2.00)	*0.04*
Micturition burn	17.6 (114)	16.1 (41)	18.7 (73)	0.83 (0.53-1.30)	0.4
Clinical signs:					
Vaginal discharge	38.2 (247)	48.6 (124)	31.5 (123)	2.06 (1.47-2.90)	*<0.0001*
Coloured discharge	15.5 (100)	23.9 (61)	10.0 (39)	2.84 (1.78-4.53)	*<0.0001*
Malodorous discharge	4.2 (27)	5.1 (13)	3.6 (14)	1.45 (0.62-3.35)	0.35
White discharge	22.6 (146)	24.3 (62)	21.5 (84)	1.17 (0.79-1.74)	0.4

Table 4 Performance comparison of different flowcharts for diagnosing cervicitis and vaginitis among pregnant women attending antenatal clinics. Libreville 1994–5

	Score*	Algorithm in 2 steps†	
Cervicitis:	*Score 3/6*	*Flowchart with leucocyte count*	*Flowchart with CT Ag detection*
Sensitivity	74.0	67.1	83.6
Specificity	50.1	57.1	63.4
Positive predictive value	15.9	16.6	22.5
Negative predictive value	93.8	93.2	96.8
Well classified rate	52.8	58.2	65.6
Vaginitis:	*Score 3/6*	*(score >2 treat only for cervicitis)*	*(score >2 treat for cervicitis and vaginitis if vaginal discharge is notified*
Sensitivity	47.8	57.3	81.2
Specificity	65.2	80.1	62.7
Positive predictive value	47.3	65.2	58.6
Negative predictive value	65.7	74.2	83.6
Well classified rate	58.4	71.1	70.0

*cf figure 1.
†cf figure 2.

Table 5 Performance comparison of different flow charts for screening cervical infections among pregnant women in Gabon, Haïti, and Zaïre

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Gabon score*	74	50	16	94
Gabon algorithm with leucocyte count†	67	57	16.5	93.5
Gabon algorithm with CT Ag detection†	83.5	63.5	22.5	97
Haïti score with speculum examination‡	89	43	19	96
Haïti score without speculum examination§	71	61.5	21	93
Kinshasa score**	72	73	16	—

*cf figure 1.
†cf figure 2.
‡New partner in past 6 months = 1; age <21 years = 2; not living with partner = 2; coital debut at ⩽18 years = 2; >1 sex partner in past 6 months = 2; partner ever had STD = 7; cervical discharge = 2; ⩾10 white blood cells/low power field in vaginal wet mount = 3.
Treat for cervical infection if sum of score ⩾4.
§Same score without the two last criteria.
**Living single = 5; >1 sex partner in the past year = 10; age <25 years = 14; 2 ⩽ age ⩽34 years = 11; reported vaginal discharge = 1; reported pelvic pain = 3.
Urine leucocyte esterase dipstick: + =10; ++ =12; +++ = 15.
Treat for cervical infection if sum of score >28.

and sophisticated). At the end of this first step, the patients are classified in three categories: patients with a score greater than 2 are diagnosed as having a cervical infection and will be treated adequately, and those with a score lower than 2 as not having cervical infection. Those with a score equal to 2 will be subjected to further investigations.

The second step is dependent on the existing tools. In the antenatal clinics in Libreville, it was possible to do speculum and direct microscopic examination, and also to collect cervical swabs for chlamydial antigen detection routinely. This step has to be very specific. Thus, we chose markers more specific than sensitive, such as the cervical aspect on the speculum examination, the leucocyte count on a cervical smear, or the chlamydial antigen detection (if possible). The patients having at least one cervical alteration are considered as infected and are treated adequately. If the cervix is healthy, a cervical cotton swab is collected for the chlamydial antigen detection or, if not possible, for the leucocyte count.

All women having a score lower than 2 and declaring or presenting vaginal discharge are treated for vaginitis, and for all women submitted to the second step (score=2), a vaginal smear for trichomonal and candidal examination is performed. For the women having a score greater than 2, two strategies are considered: treatment for cervicitis only and no investigation for vaginitis or treatment for cervicitis and vaginitis in the presence of vaginal discharge.

EVALUATION OF THE FLOWCHARTS

This flowchart allows the determination of the presence or absence of cervicitis using four very simple questions or clinical signs, for 61% of the patients, who were diagnosed and/or treated at the end of the first step. A gynaecological examination was prescribed to the other patients (39%). After speculum examination, 75% of all the patients were diagnosed without laboratory tests.

The final diagnostic performances of the score are presented in table 4. The flow chart in two steps with the count of leucocytes had a sensitivity of 67.1% and specificity of 57.1% and the flowchart with CT Ag detection had a sensitivity and a specificity of 83.6% and 63.4% respectively.

Discussion

In the population of pregnant women studied, the prevalences of STDs were very high: more than half of the pregnant women had cervical or vaginal infection. More than 10% were infected by *N gonorrhoeae* and/or *C trachomatis* and more than a third of these infected women were paucisymptomatic: 16.4% had no symptom (vaginal discharge or itching, micturition burn, pelvic or lumbar pain, dyspareunia); 20.5% presented only one of these symptoms. The clinical diagnosis of these severe infections is very difficult, and laboratory investigations too expensive to be applied to all patients for a screening. Therefore, it is necessary to develop alternative diagnostic strategies, as algorithms, based on symptoms but also on risk factors. These algorithms have to be very sensitive for diagnosing cervical infections because untreated infections often lead to serious consequences whereas overtreatment has very few side effects.

In Libreville, the elaboration of an alternative algorithm was conducted by the statistical analysis results of a prevalence study, modulated by the field constraints and the feasibility to integrate such flowcharts to everyday consultation. This algorithm, with a first step based on a risk assessment score and a second step based on the results of a speculum

examination and chlamydial antigen detection, was 83.6% sensitive and 63.4% specific. In this population where high prevalence rates of cervical infections (11.3%) have been found, positive and negative predictive values were 22.5% and 96.8% respectively. Using leucocyte count instead of chlamydial antigen detection, the sensitivity and specificity decreased to 67% and 58% respectively. Contrary to the previous evaluated score, this flowchart presents a higher sensitivity (81.2%) but preserves a good specificity (62.7%) for diagnosing vaginitis.

Compared with other cervicitis screening algorithms, evaluated among pregnant women in other countries (table 5), these results are interesting. In Haiti,[18] an algorithm based on the search of six risk factors and speculum and microscopic examination was 89% sensitive and 43% specific. The same risk assessment score without speculum examination (only six risk factors) was 71% sensitive and 61.5% specific. In Kinshasa,[19] another score based on risk factors and clinical signs without speculum examination but with urine leucocyte count reached a sensitivity of 72% and a specificity of 73% respectively. However, from our study, it seems that scores with more than five or six items, or weighted variables are too difficult and too long to be used routinely. The algorithm used in Libreville is very simple and quick to use for the first step, because it is based only on four variables which are easy to collect (no confidential question) and previously routinely collected during antenatal visits. This step is therefore easy to integrate into the visits for all pregnant women. The second step including a speculum examination, restricted only to 39% of the patients, requires a mini laboratory and more qualified staff: speculum examination and direct microscopic examination are feasible in all antenatal clinics; chlamydial antigen detection is done at the reference laboratory for only 25% all the patients. It is relatively easy to train healthcare workers for such strategies, as demonstrated in a previous study.[16] The diagnostic values are quite good, but this strategy remains a little expensive because of the chlamydial antigen detection (US$5). In areas where chlamydial antigen detection is not possible, the same strategy with leucocyte count instead of chlamydial antigen detection, presents lower but acceptable performances. Similar strategies with simple rapid tests for women with intermediate score would certainly constitute a good alternative.

This study illustrates that the implementation of the syndromic approach for the screening of STDs among women is a dynamic process requiring operational research in order to optimise the diagnostic value of the chosen flowcharts. This theoretical model needs to be evaluated prospectively, not only to confirm the diagnostic value but also to evaluate the feasibility, reliability, and acceptability, as well as cost effectiveness.

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